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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**IN RE: FOSAMAX (ALENDRONATE
SODIUM): PRODUCTS LIABILITY
LITIGATION**

THIS DOCUMENT RELATES TO:

*Faye Elizabeth Shevel and W. Lee Shevel v.
Merck Sharp & Dohme Corp.,*

Civil Action No. 13-cv-4577

MDL No. 2243

Civ. Action. No. 08-08 (JAP)

ANSWER AND ADDITIONAL DEFENSES
OF MERCK SHARP & DOHME CORP.;
DEMAND FOR JURY TRIAL

Defendant, Merck Sharp & Dohme Corp. (“Merck”), with its principal place of business located at One Merck Drive, Whitehouse Station, Hunterdon County, New Jersey, by and through its undersigned attorneys, hereby answers the Complaint (“Complaint”). Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below.

I. INTRODUCTION

1. Merck admits that Plaintiffs purport to bring a civil action for damages, but denies that there is any legal or factual basis for same. Merck denies the remaining allegations of Paragraph 1.

II. JURISDICTION AND VENUE

2. The allegations of Paragraph 2 are conclusions of law to which no response is required. To the extent that a response is required, Merck admits, for jurisdictional purposes only, that Plaintiff seeks in excess of \$75,000.

3. The allegations of Paragraph 3 are conclusions of law to which no response is required. To the extent that a response is required, Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 3, except that Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey.

4. The allegations of Paragraph 4 are conclusions of law to which no response is required. To the extent that a response is required, Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 4.

5. The allegations of Paragraph 5 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies the allegations of Paragraph 5, except admits that on May 23, 2011, the Judicial Panel on Multidistrict Litigation (“MDL Panel”) issued an order transferring 36 Fosamax products liability cases to the United States District Court for the District of New Jersey for coordinated pretrial proceedings under 28 U.S.C. § 1407. *In Re: Fosamax (Alendronate Sodium) Products Liability Litigation*, MDL No. 2243.

III. PARTIES

6. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity as to the residency of the plaintiffs. Merck admits that Plaintiffs purport to bring a civil action for damages, but denies that there is any legal or factual basis for same. Merck denies the remaining allegations of Paragraph 6.

7. Merck admits the allegations of Paragraph 7.

8. Merck denies each and every allegation of Paragraph 8, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

9. Merck denies each and every allegation of Paragraph 9, except that Merck admits that it is registered to do business in the State of Arizona and that Merck distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

10. Merck is without knowledge as to what is meant by “substantial revenue,” so the allegations of Paragraph 10 are denied.

IV. BACKGROUND

11. Merck denies each and every allegation of Paragraph 11, except that it admits that Plaintiffs purport to bring this action for damages, but denies that there is any legal or factual basis for same.

12. Merck denies each and every allegation of Paragraph 12, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck respectfully refers the Court to the Physician’s Desk Reference (“PDR”) for FOSAMAX® for its actual language and full text.

13. Merck denies each and every allegation of Paragraph 13, except that Merck admits that it marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

14. Merck is without knowledge as to what is meant by “substantial revenue,” so the allegations of Paragraph 14 are denied.

15. Merck is without knowledge as to what is meant by “consequences,” so the allegations of Paragraph 15 are denied.

16. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 16 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 16.

17. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 17 inconsistent with that prescribing information.

18. Merck denies each and every allegation of Paragraph 18, except that Merck admits that FOSAMAX® product sales in 2008 amounted to approximately \$1.55 billion.

V. SUMMARY OF THE CASE

19. Merck denies each and every allegation of Paragraph 19, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text.

20. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 22.

23. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 23.

24. Merck denies each and every allegation of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27, except that it admits that Merck collects information on adverse experiences that are temporally associated with a patient's treatment with FOSAMAX® and reports those adverse experiences to the FDA without regard to whether FOSAMAX® or some other medications or conditions caused such adverse experiences. Merck further denies that there is any causal connection between FOSAMAX® and any adverse experience reports of hardness, brittleness, or fracturing of bone, or between FOSAMAX® and Plaintiff's alleged injuries.

28. Merck denies each and every allegation of Paragraph 28, except that it admits that Schneider published an article entitled, "Should Bisphosphonates Be Continued Indefinitely? An Unusual Fracture in a Healthy Woman on Long-Term Alendronate," *Geriatrics*, Jan.; 61(1):31-3 (2006) and respectfully refers the Court to said article for its actual language and full text.

29. Merck denies each and every allegation of Paragraph 29.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33.

34. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX® and Alendronate. Merck denies the remaining allegations in Paragraph 34.

35. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX® and Alendronate. Merck denies the remaining allegations in Paragraph 35.

36. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX® and Alendronate. Merck denies the remaining allegations in Paragraph 36.

37. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX® and Alendronate. Merck denies the remaining allegations in Paragraph 37.

VI. COUNTS

COUNT I

PRODUCTS LIABILITY – DEFECTIVE DESIGN

38. Merck repleads its answers to Paragraphs 1 through and including 37, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

39. Merck denies each and every allegation of Paragraph 39, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

40. Merck denies each and every allegation of Paragraph 40, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff allegedly consumed.

41. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT II

PRODUCTS LIABILITY FAILURE TO WARN

49. Merck repleads its answers to Paragraphs 1 through and including 48, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

50. The allegations of Paragraph 50 state a legal conclusion to which no response is required. To the extent that a response is required, Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules and denies each and every allegation of Paragraph 50, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

51. Merck denies each and every allegation of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52.

53. Merck denies each and every allegation of Paragraph 53.

54. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57, except that it is without knowledge or information sufficient to form a belief as to the knowledge possessed by Plaintiff.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper

COUNT III

NEGLIGENCE

62. Merck repleads its answers to Paragraphs 1 through and including 61, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

63. The allegations in Paragraph 63 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

64. Merck denies each and every allegation of Paragraph 64, including each and every allegation contained in subparts (a) through (f).

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT IV

STRICT LIABILITY

68. Merck repleads its answers to Paragraphs 1 through and including 67, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

69. Merck denies each and every allegation of Paragraph 69, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

70. Merck denies each and every allegation of Paragraph 70, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

71. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 71.

72. Merck denies each and every allegation of Paragraph 72.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck denies each and every allegation of Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT V

BREACH OF EXPRESS WARRANTY

80. Merck repleads its answers to Paragraphs 1 through and including 79, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

81. Merck denies each and every allegation of Paragraph 81 and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

84. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

86. Merck denies each and every allegation of Paragraph 86.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT VI

BREACH OF IMPLIED WARRANTY

87. Merck repleads its answers to Paragraphs 1 through and including 86, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

88. Merck denies each and every allegation of Paragraph 88 and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that the FDA approved FOSAMAX® as safe and effective for its intended uses subject to the information contained in its prescribing information.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 90.

91. Merck denies each and every allegation of Paragraph 91.

92. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 92.

93. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

COUNT VII

ARIZONA CONSUMER FRAUD ACT (A.R.S. § 44-1521, et seq.)

96. Merck repleads its answers to Paragraphs 1 through and including 95, and by this reference hereby incorporates the same herein in this Paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

97. The allegations in Paragraph 97 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

98. Merck denies each and every allegation of Paragraph 98, except that Merck admits that it manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

102. Merck denies each and every allegation of Paragraph 102.

103. Merck denies each and every allegation of Paragraph 103.

104. Merck denies each and every allegation of Paragraph 104, except that Merck states that it is without knowledge as to whether Plaintiff was prescribed or provided FOSAMAX® and by whom or whether she consumed FOSAMAX® and as to the reasons for her alleged consumption of FOSAMAX®.

105. Merck denies each and every allegation of Paragraph 105.

106. Merck denies each and every allegation of Paragraph 106.

107. Merck denies each and every allegation of Paragraph 107.

108. Merck denies each and every allegation of Paragraph 108.

109. Merck denies each and every allegation of Paragraph 109.

110. Merck denies each and every allegation of Paragraph 110.

111. Merck denies each and every allegation of Paragraph 111.

112. Merck denies each and every allegation of Paragraph 112.

113. Merck denies each and every allegation of Paragraph 113.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

RELIEF REQUESTED

WHEREFORE, Merck denies that Plaintiffs are entitled to any of the relief requested, including the relief requested in subparts A through F, and respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

ADDITIONAL DEFENSES

Discovery and investigation may reveal that any one or more of the following additional defenses should be available to Merck in this matter. Merck, therefore, asserts said additional defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof

of all claims and allegations contained in Plaintiffs' Complaint that Merck has not expressly admitted. Further answering and by way of additional defense, Merck states as follows:

FIRST ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND ADDITIONAL DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD ADDITIONAL DEFENSE

This case is more appropriately brought in a different venue.

FOURTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH ADDITIONAL DEFENSE

Plaintiffs are barred from recovering against Merck because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by applicable federal law, including the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

SIXTH ADDITIONAL DEFENSE

To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to its prescribing physician. To the extent that New Jersey law is found to apply to

Plaintiffs' claims, Plaintiffs' claims are barred because Merck has discharged its duty to warn under N.J.S.A. 2A:58C-4 in its warning to prescribing physicians.

SEVENTH ADDITIONAL DEFENSE

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned or reduced in accordance with the applicable law.

EIGHTH ADDITIONAL DEFENSE

The injuries and damages, if any, sustained by Plaintiffs resulted in whole or in part from their own contributory or comparative negligence and any damages recovered should be reduced and/or barred in accordance with the applicable law.

NINTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiffs knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH ADDITIONAL DEFENSE

If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH ADDITIONAL DEFENSE

To the extent that Plaintiffs seek punitive damages, such claims are barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST ADDITIONAL DEFENSE

Plaintiffs' claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND ADDITIONAL DEFENSE

Plaintiffs' claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD ADDITIONAL DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part by failure to prevent or mitigate damages.

TWENTY-FIFTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH ADDITIONAL DEFENSE

With respect to each and every cause of action, Plaintiffs cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiffs' claims to a negligence cause of action.

TWENTY-SEVENTH ADDITIONAL DEFENSE

All activities of Merck as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiffs' claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH ADDITIONAL DEFENSE

With respect to each and every cause of action, Plaintiffs are not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH ADDITIONAL DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the Constitution of the United States of America and the Constitutions of the State of New Jersey and the State of Arizona.

THIRTIETH ADDITIONAL DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiffs' claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST ADDITIONAL DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was manufactured and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND ADDITIONAL DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD ADDITIONAL DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH ADDITIONAL DEFENSE

Plaintiffs have not sustained an ascertainable loss of property or money.

THIRTY-FIFTH ADDITIONAL DEFENSE

Plaintiffs have not suffered any actual injury or damages.

THIRTY-SIXTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH ADDITIONAL DEFENSE

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiffs for any amounts received from collateral sources.

THIRTY-EIGHTH ADDITIONAL DEFENSE

Plaintiffs' claims of fraud are not pleaded with the required particularity.

THIRTY-NINTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating prescription drugs, including FOSAMAX®, and is specifically charged with determining the content of warnings and labeling for prescription drugs.

FORTIETH ADDITIONAL DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

FORTY-FIRST ADDITIONAL DEFENSE

There is no causal relationship between Merck or its activities described in the Complaint and any injuries or damages allegedly sustained by Plaintiffs.

FORTY-SECOND ADDITIONAL DEFENSE

To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

FORTY-THIRD ADDITIONAL DEFENSE

To the extent that New Jersey law applies to Plaintiffs' claims and to the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any source for injuries in the Complaint, such benefits are not recoverable in this action under N.J.S.A. 2A:15-97.

FORTY-FOURTH ADDITIONAL DEFENSE

The defendant is not guilty of negligence and violated no duty owing to Plaintiffs.

FORTY-FIFTH ADDITIONAL DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs lack capacity and/or standing to bring such claims.

FORTY-SIXTH ADDITIONAL DEFENSE

The extent of any risk associated with the use of Merck's product, the existence of which is not admitted, was, at the time of the distribution of the product by Merck, unknown and could not have been known by the use of ordinary care by Merck.

FORTY-SEVENTH ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrine of accord and satisfaction, res judicata, payment and/or release.

FORTY-EIGHTH ADDITIONAL DEFENSE

Plaintiffs' damages are barred or reduced by the doctrine of avoidable consequences.

FORTY-NINTH ADDITIONAL DEFENSE

With respect to Plaintiff's demand for punitive damages, Merck specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards which arose in the decisions of *BMW of North America v. Gore*, 517 U.S. 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001), *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008).

FIFTIETH ADDITIONAL DEFENSE

To the extent that Plaintiffs attempt to seek equitable relief, Plaintiffs are not entitled to such relief because Plaintiffs have an adequate remedy at law.

FIFTY-FIRST ADDITIONAL DEFENSE

Plaintiffs are barred from recovery and/or Plaintiffs' recovery is limited pursuant to the Comparative Negligence Act, N.J.S.A. 2A:15-5.1, *et seq.* to the extent that New Jersey law applies to Plaintiffs' claims.

FIFTY-SECOND ADDITIONAL DEFENSE

Merck denies any liability on its part, but if Merck is ultimately found liable to Plaintiffs, then it shall only be liable for its equitable share of Plaintiffs' recovery since any liability which would be found against it will be insufficient to impose joint liability. In the alternative, the liability, if any, of Merck is limited by and pursuant to the New Jersey Joint Tortfeasor Contribution Act, N.J.S.A. 2A:53A-1, *et seq.* to the extent that New Jersey law applies to Plaintiffs' claims.

FIFTY-THIRD ADDITIONAL DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel or waiver.

FIFTY-FOURTH ADDITIONAL DEFENSE

To the extent that New Jersey law applies to Plaintiffs' claims, Merck asserts all defenses available to it pursuant to N.J.S.A. 2A:58C-1, *et seq.*, otherwise known as the New Jersey Product Liability Act.

FIFTY-FIFTH ADDITIONAL DEFENSE

To the extent that New Jersey law applies to Plaintiffs' claims, those claims are confined to those available under the New Jersey Product Liability Act.

FIFTY-SIXTH ADDITIONAL DEFENSE

Venue in this case may be improper.

FIFTY-SEVENTH ADDITIONAL DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FIFTY-EIGHTH ADDITIONAL DEFENSE

To the extent the Court finds that any of Plaintiffs' claims are governed by the law of a state other than New Jersey, Merck asserts all affirmative defenses available to it under that other state's law.

FIFTY-NINTH ADDITIONAL DEFENSE

A.R.S. § 12-701 further bars Plaintiffs' claim for punitive damages.

SIXTIETH ADDITIONAL DEFENSE

Plaintiffs cannot state a claim under the Arizona Consumer Fraud Act because they have not relied on any representations by Merck and/or have not suffered any consequent and proximate injury.

In so much as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing the Complaint with prejudice and awarding Merck its reasonable costs and disbursements, including reasonable attorneys' fees as may be available by law, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

Dated: August 28, 2013

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 28, 2013, the foregoing was filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system on all counsel of record.

/s/ Karen A. Confoy